

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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PUBLIC PATENT FOUNDATION, INC.	:	
	:	
Plaintiff,	:	Civil Action 1:09-cv-05471-RJH
	:	
v.	:	
	:	
McNEIL-PPC, INC.,	:	ECF CASE
	:	
Defendant.	:	
-----	X	

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANT'S MOTION TO DISMISS

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INTRODUCTION

Plaintiff, Public Patent Foundation (“PUBPAT”), is a New York-based, non-profit legal services organization affiliated with the Benjamin N. Cardozo School of Law, where PUBPAT's Executive Director is also a member of the faculty. Compl., ¶ 7. PUBPAT exists to represent the public interest in the patent system. Compl., ¶ 8. PUBPAT believes that the public interest is significantly harmed by false patent marking, and that the public interest would be well-served by meaningful enforcement of the false marking statute as Congress intended. This is why PUBPAT has sued McNeil-PPC, Inc. (“McNeil”) and other commercial entities who intentionally or recklessly mark or promote their products with false patent information.¹

In addition to arguing that PUBPAT lacks Constitutional standing to bring this case, McNeil claims that any suggestion it intended to deceive the public by falsely labeling and promoting its products as “patented” is entirely implausible. In reality, however, McNeil's false marking is simply the latest chapter in its long history of attempting to deceive the public about Tylenol. See, e.g., S. Asrani, MD, *The FDA's headache: Tylenol*, 2009 (Ravicher dec., Ex. 1). In the past, McNeil promoted Tylenol as the safest over-the-counter medication for pain and fever relief, despite the fact that “Acetaminophen [the active ingredient in Tylenol] causes three times as many cases of liver failure as all other drugs combined, and is the most common cause of acute liver failure in the United States, accounting for 39% of cases.” See Tylenol, Wikipedia (Ravicher dec., Ex. 2) (footnote omitted).

When asked in 1998, “Why not warn [customers] about possible liver failure?” McNeil

¹ Some of PUBPAT's other work on behalf of the public interest includes challenging patents granted on human genes relating to breast and ovarian cancer and advocating for patent reform before Congress, which has called PUBPAT's Executive Director twice to testify on the subject.

responded, “Organ-specific warnings would confuse people.” Ravicher dec., Ex. 1 at 20. Eventually, however, the truth caught up with McNeil. As a recent FDA report concluded: “The narrow therapeutic-to-toxic ratio [for acetaminophen] is particularly troublesome because surveys indicate that people routinely and knowingly take more than the recommended dose of over-the-counter pain relievers.” See B. M. Kuehn, *FDA Focuses on Drugs and Liver Damage: Labeling and Other Changes for Acetaminophen*, 302 JAMA 4:369, 370 (July 22/29, 2009) (Ravicher dec., Ex. 3); see also S. Saul, *New Warnings Proposed For Over-the-Counter Drugs*, New York Times, A.18, December 20, 2006 (Ravicher dec., Ex. 4). With overwhelming evidence of its safety problems beginning to resonate with the FDA and the public, McNeil eventually abandoned its strategy of marketing Tylenol as “safer” than other alternatives. See *Advertising Law*, Manatt, Phelps & Phillips, LLP, 5-6 (July 27, 2009) (Ravicher dec., Ex. 5) (“Johnson & Johnson faces the delicate task of reassuring consumers about the safety of Tylenol without overstating its case, which could generate a backlash or continue to keep safety concerns in the public eye.”)). But then the question was how to continue to lead consumers to think Tylenol is the best pain reliever?

The solution that avoided drawing attention to Tylenol's safety problems was to instead promote Tylenol as “patented.” And that's exactly what McNeil decided to do, launching new website content, radio ads, and product labeling to tout the supposed “patented” technology in Tylenol. The only problem was that Tylenol was not – in fact – patented. To be sure, shortly after PUBPAT initiated this suit, McNeil abruptly ended its “Tylenol is patented” advertising campaign. Compare, Compl., ¶¶ 32-33 with November 5, 2009 version of <http://www.tylenol.com/different/index.jhtml> (Ravicher dec., Ex. 6). Thus, just like its “safest”

advertising campaign, McNeil's more recent "patented" campaign was also false, and – as alleged by PUBPAT in its complaint – was done with the intent to mislead the public. The problem for McNeil is that Congress does not like companies that falsely mark and advertise their products as patented, and it is an act of Congress that gives PUBPAT a basis for this case.

While McNeil's false "Tylenol is patented" campaign involved at least three products, radio ads, and the www.Tylenol.com website, all of which are specifically alleged with detailed facts in PUBPAT's complaint, for purposes of defeating McNeil's motion to dismiss, it is sufficient and simpler to focus on just one of the products, McNeil's Tylenol Arthritis Pain Caplets ("the APC product"), as a representative example.

As of mid-2009, the APC product was marked, "U.S. Patent Nos. 4,968,509 and 5,004,613." Compl., ¶15). However, those patents expired in November 2007 and April 2006. McNeil Mem., 4. The APC product also contained the word "PATENTED" in large red font on the front of the package. Compl., Ex. B. In addition, the Tylenol web site, operated by McNeil, contained an image of the APC product package, including its red "PATENTED" language. Compl., Ex. D and ¶31. And, McNeil stated on its web site and in radio ads that its Tylenol products include "patented technology." McNeil Mem., 20 (acknowledging "McNeil's statements on its Web site or on the radio"). These false markings are particularly egregious because, "[a]s a sophisticated company that ... employs multiple in-house patent attorneys and regularly litigates patent infringement and false advertising cases, [McNeil] knows, or reasonably should know, of the requirements of 35 U.S.C. § 292." Compl., ¶ 24. These facts alleged in PUBPAT's complaint form a plausible claim for false marking with respect to the APC product. Similar allegations with respect to the other products, the website and the radio

advertisements are in the complaint as well.

McNeil incorrectly asserts in its brief that PUBPAT seeks \$500 for each of McNeil's violations. McNeil Mem., 9. This is not true. All that PUBPAT asks is that the Court "[d]etermine an *appropriate 'fine,' not more than \$500 per offense, but sufficient to appropriately penalize* [McNeil's] violations of § 292(a), and to deter [McNeil] and others similarly situated from violating § 292(a) in the future." Compl., Prayer for Relief at (3). Moreover, even if PUBPAT were to aggressively seek the maximum penalty available under the statute, there would still be nothing unsavory about such a financially-motivated lawsuit. Indeed, as Federal Circuit Judge Moore explained from the bench during oral argument just last month:

Given that false marking would cause competition to decrease, people might not compete because they see the patent number, ..., then ***there's nobody who really has the incentive to bring the false marking [case],*** and we don't know how deleterious this is on competition, generally. ***So maybe we ought to be -- just like the statute does -- rewarding the 'troll*** (with the green brief) who comes forward because he's going to eliminate these people who are eliminating competition.²

The purpose of *qui tam* statutes is to enlist the aid of private parties – like PUBPAT – in achieving compliance with the law when the government does not wish to, or does not have the resources to, do so itself. By bringing this case, PUBPAT is doing precisely what Congress hoped parties would do when it passed in 1842, and re-passed in 1870, and re-passed in 1952, and re-passed in 1994 the “any person” language of the false marking statute.

ARGUMENT

McNeil makes three arguments in favor of dismissal. First, McNeil argues that PUBPAT

² Forest Group, Inc. v. Bon Tool Co., Case No. 2009-1044 (Fed. Cir., Oct. 7, 2009), recorded audio at 15:58-16:25 (available at <http://oralarguments.ca9.uscourts.gov/mp3/2009-1044.mp3>).

lacks Constitutional standing to bring this action, despite the fact that the false marking statute has authorized suit by “any person” since 1842. Second, McNeil argues that PUBPAT's complaint fails to meet the pleading requirements of Fed. R. Civ. P. 8 and 9(b), even though PUBPAT's complaint specifically identifies the what, when, where, and how of McNeil's false marking, and details McNeil's numerous, simultaneous expressions of patent protection that support inferring an intent to deceive. Third, McNeil argues that marking a product with an expired patent or a patent on a method or machine for producing the product cannot constitute false marking, despite the existence of controlling authority that (i) it is false to mark a product with a patent that does not “cover” the product and (ii) expired and method/machine for production patents cannot, under any circumstances, “cover” a product. For these and other reasons, each of McNeil's arguments is unavailing and its motion to dismiss should be denied.³

I. MCNEIL'S FALSE MARKING HAS INJURED THE SOVEREIGN INTEREST OF THE UNITED STATES AND THE PUBLIC INTEREST PUBPAT EXISTS TO REPRESENT, EITHER OF WHICH SEPARATELY PROVIDES PUBPAT WITH STANDING TO BRING THIS *QUI TAM* ACTION

McNeil does not dispute that the false marking statute expressly provides PUBPAT with standing to bring this case. Nor could it, as the statute unequivocally states, “Any person may sue for the penalty.” 35 U.S.C. § 292(b). Rather, McNeil argues that the statute violates the Constitutional Article III standing requirement, when it purports to allow “any person” - including PUBPAT – to sue.⁴ McNeil's argument that PUBPAT lacks standing to bring this action is wrong for at least two reasons. First, PUBPAT has standing as a relator of the United

³ To the extent the Court finds any merit in McNeil's motion to dismiss, PUBPAT would respectfully request leave to amend its complaint to add even more specific allegations regarding PUBPAT's standing and/or McNeil's deceitful intent.

States' injury to its sovereignty resulting from McNeil's violation of the United States' laws. PUBPAT alleges this injury repeatedly in its complaint. Compl., ¶¶ 2, 29-30, 36, 41 (“Defendant has violated 35 U.S.C. § 292(a)”). Second, PUBPAT has standing in its own right resulting from the injury caused by McNeil's false marking to the public interest that PUBPAT exists to represent. PUBPAT alleges this injury, which inherently results from McNeil's falsely marking products for the purpose of deceiving the public, repeatedly in its complaint. *Id.* at ¶¶ 25-27, 35.

A. Injury To The Sovereign Interest Of The United States Caused By McNeil's False Marking Provides PUBPAT Standing

Qui tam statutes – like the false marking statute in this case – have been part of the American legal landscape from the very founding of our nation. The Supreme Court conclusively settled the issue of whether *qui tam* statutes (including specifically the false marking statute at issue in this case) satisfy Constitutional standing requirements in Vermont Agency of Nat'l Res. v. United States ex rel. Stevens, where it ruled that a relator need not have suffered injury itself, but instead has standing under the doctrine of assignment because *qui tam* statutes “can reasonably be regarded as effecting a partial assignment of the Government's damages claim” and, as a result of this assignment, “the United States' injury in fact suffices to confer standing on [the relator].” *Id.*, 529 U.S. 756, 773-74 (2000). As the Supreme Court explained, “the long tradition of *qui tam* actions [was] well nigh conclusive with respect to . . . whether *qui tam* actions were cases and controversies of the sort traditionally amenable to, and resolved by, the judicial process.” *Id.* at 777. Importantly, Vermont Agency specifically

⁴ While this may not be a facial Constitutional attack on the statute, it is indeed an “as applied” Constitutional attack, because McNeil is arguing that if the statute is applied in this case to provide PUBPAT standing as “any person” then such would violate Article III.

identified § 292 as one of the other remaining *qui tam* provisions in U.S. law, meaning it, too, provides Constitutionally sufficient standing to relator-assignees, like PUBPAT. Id. at 768, n.1.

Other courts have confirmed this conclusion. In Pequignot v. Solo Cup Co., the court performed a detailed analysis of standing under the false marking statute in light of Vermont Agency and held that:

§ 292(b) is a *qui tam* statute. It defines a wrong to the government as the false patent marking in violation of § 292(a). It imposes a statutory penalty of up to \$500 per violation. It provides that "any person may sue for the penalty," regardless of whether or not such a person is personally harmed. Finally, it allows the suing person to receive half of the recovery from the suit, with the remainder going to the government.

Id., 2009 U.S. Dist. LEXIS 26020 at *18 (E.D. Va. March 27, 2009) ("Solo Cup II"). The Solo Cup II court continued to observe as follows:

In addition, the Supreme Court and those courts that have adjudicated cases under § 292 have explicitly termed § 292(b) a *qui tam* statute. See Vermont Agency, 529 U.S. at 768 n.1 (listing § 292(b) as one of the few remaining "*qui tam* statutes [that] remain on the books"); Boyd v. Schildkraut Giftware Corp., 936 F.2d 76, 79 (2d. Cir. 1991) (noting that § 292 "is enforceable by a *qui tam* remedy"); Brose v. Sears, Roebuck & Co., 455 F.2d 763, 765 (5th Cir. 1972) (describing an action under § 292(b) as one by a "*qui tam* informer"); Winne v. Snow, 19 F. 507, 508 (S.D.N.Y. 1884) (describing the suit before it as "a *qui tam* action to recover a penalty under [the false marking statute]"). In addition, the Senate Report issued with the statute's revision in 1952 described the portion of the statute that provides for a private suit as an "informer action," a term synonymous with a *qui tam* law. S.R. 82-1979 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2403. Solo has cited to no authority holding that § 292(b) is not a *qui tam* statute, and this Court has found none.

Id. at 18-19. Accordingly, based on the vast weight of authority, PUBPAT clearly has Constitutionally sufficient standing to pursue this action against McNeil's false marking because that false marking violated the statute, thus injuring the sovereign interest of the United States, and the *qui tam* provision of the false marking statute, § 292(b), validly assigns the right to

pursue that injury to the “any person” who sues, in this case PUBPAT.

McNeil's only argument to refute this point rests solely on the Stauffer case, but McNeil omits several important facts about that decision. First, it is a complete outlier; no other court has ever dismissed a false marking case for lack of standing, including the Federal Circuit, which has heard several false marking cases over the years and never once even hinted that non-competitor plaintiffs like PUBPAT lack standing. See, e.g., Solo Cup Co., 2009 U.S. Dist. LEXIS 26020 at *15 (“[A] qui tam statute does not require that the relator suffer an injury before he or she pursues an action”); Harrington v. CIBA Vision Corp., No. 3:08-cv-251 (W.D.N.C.) (docket showing May 22, 2009, denial of motion to dismiss on standing grounds (Dkt. No. 16) after extended briefing including consideration of Stauffer (Dkt. No. 48)); Clontech Labs., Inc. v. Invitrogen Corp., 406 F.3d 1347 (Fed. Cir. 2005); High Frequency Prods. v. Wynn's Climate Sys., 91 F.3d 167 (Fed. Cir. 1996); Arcadia Machine & Tool, Inc. v. Sturm, Ruger & Co., 786 F.2d 1124 (Fed. Cir. 1986).

Second, Stauffer is currently on appeal to the Federal Circuit and the United States, who was denied leave to intervene in the case at the district court level to support the plaintiffs standing, is participating in the appeal in order to have the decision reversed. Stauffer v. Brooks Brothers, 09-1428, -1430, -1438 (C.A.F.C.) (United States is movant-cross appellant). To be sure, the United States strongly supports the right of *qui tam* plaintiffs like PUBPAT to bring false marking actions and has intervened in several cases — besides this one — to oppose the exact lack-of-standing argument made by McNeil here.⁵ Like the government and every other

⁵ The U.S. has intervened, sought to intervene or indicated that it wishes to consider intervening in this case and at least each of: Public Patent Foundation, Inc. v. GlaxoSmithKline Consumer Healthcare, L.P., 1:09-cv-05881 (S.D.N.Y.); Matthew A. Pequignot v. Solo Cup Co., 1:07-

court to address the issue, PUBPAT respectfully submits that Stauffer was wrongly decided and that the mountain of evidence to the contrary – that *qui tam* plaintiffs like PUBPAT do indeed have standing to bring false marking cases – is persuasive on this point.

B. Injury To The Public Interest Represented By PUBPAT Caused By McNeil's False Marking Provides PUBPAT Standing

Unabated false marking offers many potential advantages to the mis-marker: winning over consumers, building a superior brand associated with innovativeness, implying that the mis-marked product has been reviewed and approved by the federal government, or implicitly threatening actual or potential competitors with allegations of patent infringement. Thus, when products are falsely marked or advertised as “patented,” such false marking or false advertising provides these potential benefits to the false marker/advertiser without any commensurate justification and, as such, creates the potential to negatively impact the marketplace, the public interest, and the integrity of the patent system. Since PUBPAT is a public charity that exists to represent the public interest, the harm caused by false marking, such as that committed by McNeil in this case, injures PUBPAT's interests directly. That direct injury to the interests it represents provides PUBPAT with standing to bring actions like this one for false marking.

1. False Marking Harms the Public

The Federal Circuit has recognized the harm to society caused by false marking, saying,

Congress intended the public to rely on marking as “a ready means of discerning the status of intellectual property embodied in an article of manufacturer or

cv-00897 (E.D. Va.); James M. Harrington v. CIBA Vision Corp., 3:08-cv-00251 (W.D.N.C.);

North Carolina Farmers' Assistance Fund, Inc. v. Monsanto Co., 1:08-cv-0409 (M.D.N.C.);

Brule Res.v. A.O. Smith, 2:08-cv-1116 (E.D.W.I.); Stauffer v. Brooks Brothers, 1:08-cv-10369

(S.D.N.Y.); and Juniper Networks v. Shipley, 4:09-cv-00696 (N.D. Cal.).

design.” Bonito Boats, 489 U.S. at 162, 109 S.Ct. 971. Lear articulates federal patent policy, recognizing an “important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain.” 395 U.S. at 670, 89 S.Ct. 1902. That interest is clearly injured by false marking because the act of false marking misleads the public into believing that a patentee controls the article in question (as well as like articles), externalizes the risk of error in the determination, placing it on the public rather than the manufacturer or seller of the article, and increases the cost to the public of ascertaining whether a patentee in fact controls the intellectual property embodied in an article.

Clontech Labs., Inc. v. Invitrogen Corp., 406 F.3d 1347, 1356-1357 (Fed. Cir. 2005) (footnote omitted). The false marking statute aims to protect the public from this risk of being misled by false patent markings, which not only can create incorrect conclusions about whether a particular product is controlled by a single party, but can also lead consumers to erroneously attribute innovative, quality, safety, or performance characteristics to the falsely marked product. For these reasons, the false marking statute protects the interest of the public in not being misled into thinking a certain product – falsely marked as patented – is controlled by a single party, or is better or more innovative than other products available to them in the marketplace. This public interest is one served by PUBPAT and thus false marking injures that interest. Such provides PUBPAT with specific injury sufficient to confer standing to bring this case.

2. False Marking Harms Honest Competitors and Competition

False marking harms law-abiding competitors with unpatented articles. Such competitors who do not also falsely mark their products face the prospect that consumers will be misled into thinking their competitor's falsely marked product is more innovative or modern. Such conduct harms both consumers and law-abiding competitors. In addition, false marking also harms legitimate competitors by exerting a chilling effect on their willingness to enter the market for, or improve upon, the falsely marked product. For example, a competitor that has a cheaper method

of manufacturing a product might be discouraged from entering the market if the product were adorned with a false patent declaration. Similarly, if an innovator discovers an improvement to the product, that innovator might be discouraged from introducing the improvement for fear that the false marking might represent a blocking patent on the improvement. At a minimum, such false designations force legitimate competitors and innovators to spend scarce resources to investigate and disprove these false assertions, which harms competition and the general public. Again, this public interest is one served by PUBPAT and since false marking injures that interest, it provides PUBPAT with specific injury sufficient to confer standing to bring this case.

3. False Marking Harms Legitimate Patentees and Risks Decreasing the Incentive to Innovate Provided by the Patent Grant

In addition to the harm caused to consumers and competitors, perhaps one of the largest – and most overlooked – harms caused by false marking is to legitimate patentees. Imagine two competitors in a marketplace, one has a patent on her product, while the other does not. Both mark their products as patented, the first being justified in doing so, because she earned that privilege by having a currently valid patent, but the second not being justified in doing so, either because he never had a patent or any patent he did have has since expired. The marking of both products leads consumers to believe that both products are comparably innovative and, thus, of similar value. This deprives the legitimate patentee of the consumer respect and resulting commercial value that she deserves, because due to her competitor's false marking, her product doesn't stand out in the mind of the consumer as being more innovative.

By depriving patentees of one of the important benefits of earning a patent, false marking actually risks decreasing the incentive to innovate offered by the exclusive patent grant. Thus, an important function of the false marking statute is to protect the interests of legitimate

patentees in receiving the marketplace distinction they deserve so as to maintain incentives to innovate, which are important to ensuring technological advances are brought to the public. As with the above public interest, this harm caused by false marking causes specific injury to the interests represented by PUBPAT and, thus, provides PUBPAT with standing.

4. False Marking Injures the Public Interest Regardless of Whether Actual Harm is Caused in Any Particular Case

PUBPAT also submits that false marking is a serious violation of the public interest even if no harm is caused in any particular case. Stepping back for a moment, one cannot dispute that there exist countless laws in our country that serve to protect societal interests against certain behavior, even when that behavior might not actually cause any particular harm. For example, the entire category of crimes for attempting to commit another crime is justified not because any specific harm was caused by the attempt to commit crime, but because the act of even attempting to commit a crime is conduct we as citizens have decided to prohibit and meaningfully penalize. Further, many deceit based violations of the law are actionable and serious threats to the public interest even if no harm results from the deceit. For one, lying in court under oath is an act that merits significant punishment even if the lie has no effect whatsoever on the outcome of the case.

For similar reasons, even if the circumstances in any particular case of false marking – a violation of the law based on intent to deceive, not actual harm caused – are such that no actual harm can be proven to have occurred, that does not mean such conduct should be condoned by society. To the contrary, to condone such behavior with a “no harm no foul” attitude would in fact encourage such behavior when – as in the case of false marking – it offers such a substantial potential benefit to the actor. Put simply, if there were no law against it, false marking would be rampant in the marketplace because it is an activity of insubstantial cost to perform, relative to its

potential benefit.

Just imagine #2 pencils, aspirin, and even milk being labeled and advertised as patented. Surely such would cause consumer confusion, while also creating a mockery of legitimate patentees when they honestly tout their products' innovativeness as proven by their valid patents. Respect for all patents would decline, and the efficiency of the marketplace would be perverted by false and misleading information for comparing products. This is why it is important to create a deterrent effect by prohibiting and meaningfully punishing false marking, regardless of whether actual harm is caused by a specific act of false marking in any particular case.

To be sure, this is why Congress only required an intent to deceive in order to violate the false marking statute, and not actual deceit or harm. If Congress wanted to punish only those instances where false marking caused actual harm, it could have easily written the statute to achieve that goal. It didn't. If McNeil is unhappy about this, the proper course is for them to lobby Congress for a change to the law, not attempt to fashion such a requirement onto what was clearly Congress' intent. McNeil's suggestion that this Court usurp Congress' clear intent in implementing time and time again the false marking statute by finding that the statute is a violation of the Constitution should be rejected.

Lastly, the location of the anti-false marking statute within the Patent Act confirms Congress' belief regarding its importance to society. The false marking statute is contained in the same chapter of the Patent Act that contains the statutes pertaining to damages, injunctions, attorney fees, and many of the other statutes that are the most important to ensuring patents are adequately respected and infringement of patents is fairly remedied. Thus, to argue that 35 U.S.C. § 292 is somehow an obscure statute, or one that landed in the Patent Act by

happenstance or mistake is simply unsupportable. Truth be told, the prohibition against false marking lies right in the heart of the Patent Act because it, too, is a serious violation of the law that Congress intended to sanction.

II. PUBPAT'S COMPLAINT CONTAINS ALLEGATIONS THAT ARE SUFFICIENTLY SPECIFIC AND DETAILED TO SATISFY ALL APPLICABLE PLEADING REQUIREMENTS

McNeil next argues that PUBPAT's complaint is deficient under Fed. R. Civ. P. 8 because, “[a]n intent to deceive the public is a critical element of an 35 U.S.C. 292 claim” and “PubPat, however, pleads no facts in support of its allegation of deceptive intent.” McNeil Mem., 16. While McNeil is absolutely correct that Iqbal requires a pleading contain “sufficient factual matter” and that Twombly requires a pleading contain “more than labels and conclusions,” PUBPAT's complaint alleges in detail many facts that support the required intent element. Ashcroft v. Iqbal, 129 S.Ct. 1937; Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). To be sure, nothing in Iqbal requires direct, “smoking gun” evidence of intent, especially when, as here, applicable precedent states that the requisite intent is to be viewed objectively, not subjectively.

McNeil additionally argues that false marking claims are subject to Rule 9(b)'s enhanced pleading requirements, even though precedent is to the contrary, and that PUBPAT's complaint is “insufficient” to meet those heightened requirements, despite the fact that Rule 9(b) dictates that intent may be alleged generally. McNeil Mem., 17. In the end, as with the standing issue, McNeil's arguments on these points are misplaced.

A. PUBPAT's Complaint Contains Sufficient Factual Allegations Regarding McNeil's Intent To Deceive

With respect to pleading an intent to deceive, McNeil ignores the controlling effect of

Clontech, where the Federal Circuit held that intent to deceive for a false marking claim is established by objective – not subjective – criteria. Id., 406 F.3d at 1352. Under Clontech, the only elements necessary to establish the required intent to deceive are (i) fact of misrepresentation and (ii) proof that the party making it had knowledge of its falsity. Id. To further emphasize this point, the Federal Circuit said in Clontech that, “the mere assertion by a party that it did not intend to deceive will not suffice to escape statutory liability,” and that “[s]uch an assertion, standing alone, is worthless as proof of no intent to deceive where there is knowledge of falsehood.” Id.

With respect to the second prong of the Clontech intent test (knowledge of falsity), the Federal Circuit said it, too, is an objective inquiry, “in order to establish knowledge of falsity the plaintiff must show by a preponderance of the evidence that the party accused of false marking did not have a reasonable belief that the articles were properly marked (i.e. covered by a patent).” Id. at 1352-53. Thus, PUBPAT need not prove, much less allege, that McNeil had specific intent to deceive the public. To the contrary, PUBPAT need only allege that McNeil falsely marked or advertised its products, and that McNeil either knew such to be false or lacked a reasonable basis to believe such was true.

Both prongs of the Clontech intent test are specifically alleged in PUBPAT's complaint. First, PUBPAT specifically alleges the facts underlying McNeil's misrepresentations. Compl., ¶¶ 14-16. Second, PUBPAT specifically alleges that McNeil had knowledge of the falsity of those misrepresentations, or at least did not have a reasonable basis to believe they were true. Id. at ¶ 28 (“Defendant knows, or reasonably should know, that marking the above-described TYLENOL® products with false patent statements was and is illegal under Title 35 of the United

States Code. At a minimum, Defendant had and has no reasonable basis to believe that its use of the false markings was or is proper or otherwise permitted under federal law.”). There is no requirement that PUBPAT plead more to avoid a Rule 12(b)(6) dismissal. See Channel Master Corp. v. JFD Electronics Corp., 260 F. Supp. 568, 573 (E.D.N.Y. 1966) (“[Defendant] contends that the necessary element of intent was lacking. Obviously, this motion cannot be granted under Rule 12(b)(6); at best, it can be considered only as a motion for summary judgment.”); Meyer v. Rodex Sales & Servs., LLC, 2006 U.S. Dist. LEXIS 84451, *23 (D. Idaho 2006) (“RSS did in fact mismark the brochures with a patent number that did not pertain to the products featured. The fact of misrepresentation is one element that can lead to an inference of an intent to deceive and that fact exists in this case. See Clontech, 406 F.3d 1347. However, the other element needed is knowledge of the falsity. See id. The burden is on the plaintiff to prove this specific intent to deceive. RSS says the reference was inadvertent and Plaintiffs disagree. There is a genuine issue of material fact as to whether Defendant RSS had the requisite intent to deceive the public when it placed the patent number on its brochures.”).

Moreover, even if subjective intent were required, PUBPAT's complaint would still suffice. Considering, for example, the Arthritis Pain Caplet product, the complaint recites numerous facts that plausibly suggest an “intent to deceive.” First, there is the fact of the false marking itself, from which a reasonable juror could easily conclude that McNeil intended its labeling be believed, especially where (i) there is no other conceivable motivation for the false marking (the patents had long since expired, hence there was no issue of preserving damages under § 287(a)) and (ii) there is no assertion by McNeil that it lacked knowledge of the patents' expiration, or of the requirements of § 292(a). Second, there is the simultaneous labeling on the

front of the product and on the website with the word "PATENTED" in red. These markings serve absolutely no purpose under § 287(a); hence, a reasonable juror could fairly conclude that they support PUBPAT's theory of an intent to deceive. Third, there was the prominent statement on McNeil's website that its Tylenol products include "patented technology." Fourth, there are the statements about "patented technology" in the Tylenol radio ads. Fifth, there is also the fact that all of these activities suddenly ceased when McNeil was sued.⁶ Each of these facts directly contradicts McNeil's assertion that "PubPat [] pleads no facts in support of its allegation of deceptive intent."⁷

B. Rule 9(b) Is Likely Inapplicable To False Marking Actions, But Even If It Is, PUBPAT's Allegations Are Nonetheless Sufficient To Satisfy Rule 9(b)

McNeil's next basis for arguing that PUBPAT's complaint should be dismissed is that Fed. R. Civ. P. 9(b) allegedly requires "particularity" in the pleading of § 292 claims, yet courts have split on the issue, and the most established precedent actually finds that Rule 9(b) does not apply to § 292 claims. The first thing to note is that the Federal Circuit is the only Court of Appeals with jurisdiction on this issue. Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions, 482 F.3d 1347, 1356 (Fed. Cir. 2007) (application of Rule 9(b) to issues "unique to patent law" is a question of Federal Circuit law). Unfortunately, the Federal Circuit has not yet addressed it, although several district courts have. In Astec Am., Inc. v. Power-One,

⁶ While these post-commencement activities are not presently alleged in the complaint, PUBPAT submits that McNeil cannot reasonably dispute them.

⁷ The related, simultaneous false representations alleged in the complaint – on the front and back of the products, on McNeil's website, and in McNeil's radio ads – distinguish this case from the Douglas and Max Impact cases cited by McNeil. McNeil Mem., at 17.

Inc., the Eastern District of Texas held that Rule 9(b) does not apply to claims under § 292. No. 6:07-cv-464, 2008 U.S. Dist. LEXIS 30365, at *33 (E.D. Tex., Apr. 11, 2008). Similarly, in Third Party Verification, Inc. v. Signaturelink, Inc., the Middle District of Florida held the same and noted that, “[t]here is no case law that has required the Rule 9 level of pleading to claims for false marking.” Id., 492 F. Supp. 2d 1314, 1327 (M.D. Fla. 2007).

McNeil correctly points out that the Northern District of California recently held in Juniper Networks v. Shipley that Rule 9(b) did apply to § 292 claims. Id., 2009 U.S. Dist. LEXIS 40978 (N.D. Cal., May 14, 2009). However, that court cited non-§ 292 cases as justification to depart from Astec Am. and erroneously relied on Ninth Circuit, rather than Federal Circuit, law to do so. Id. Thus, PUBPAT respectfully submits that Juniper is both an outlier and legally unpersuasive on the Rule 9(b) issue. For one, the false marking statute is not a fraud based claim. It does not require fraud be shown, nor is fraud even mentioned in the statute. Instead, § 292 is an intent statute, and Rule 9(b) recognizes that “fraud or mistake” is different from “malice, intent, knowledge, and other conditions of a person's mind,” by treating the two categories differently (requiring particularity for “fraud”, but permitting general allegations for “intent”). Fed. R. Civ. P. 9(b).

Moreover, even if Rule 9(b) applies, PUBPAT's allegations are sufficient. PUBPAT's complaint specifically identifies the “circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b); see Compl. at ¶¶ 10-12, 14-16 (identifying the precise markings made by McNeil that are false and also identifying the precise places where McNeil distributes its falsely marked products). Rule 9(b) expressly permits “[m]alice, intent, knowledge, and other conditions of a person's mind [to] be alleged generally,” which PUBPAT also does in the complaint. Fed. R.

Civ. P. 9(b); see Compl. at ¶¶ 25-27 (generally alleging that McNeil falsely marks its products for the purpose of deceiving the public).

McNeil's reliance on Exergen Corp. v. Wal-Mart Stores, Inc. is misplaced. 2009 U.S. App. LEXIS 17311, *37 n.5 (Fed. Cir. 2009). In that case the Federal Circuit was referring to the evidence required at trial for elements that require “clear and convincing” proof. Unlike the inequitable conduct claim at issue in Exergen, no part of a § 292 action requires clear and convincing proof. Clontech, 406 F.3d at 1352. Thus, Exergen is entirely inapplicable here for two reasons: (i) this is the pleadings stage, not trial; and, (ii) the burden of proof for false marking claims is preponderance of the evidence, not clear and convincing proof.

III. FOR AN ITEM MARKED WITH SPECIFIC PATENT NUMBER(S), AN "UNPATENTED ARTICLE" UNDER §292(a) IS ONE THAT IS NOT COVERED BY AT LEAST ONE CLAIM OF EACH PATENT WITH WHICH THE ARTICLE IS MARKED

In Clontech, the Federal Circuit expressly stated that the term "unpatented article" in § 292(a) "means that the article in question is not covered by at least one claim of each patent with which the article is marked." 406 F.3d at 1352 (emphasis added). Thus, if an article is marked with several patents, at least one claim of each of those patents must “cover” the article itself, else the product is “unpatented” and the marking is false. On this point, there can be no debate that the Federal Circuit's Clontech decision controls, and under that decision the query is simple: Is the article marked with any patent that does not have at least one claim that covers the article? If so, the article is “unpatented” for purposes of § 292 and the marking of that product with the patent that does not have at least one claim that covers it is false.

A. Marking With Expired Patent Number(s) Is False Marking

McNeil's argument that previously-patented products are not "unpatented" is

unpersuasive. It relies entirely on district court decisions — Ansul (1971), FMC (2005), Moore (2000), Santa Anita (1967), and French (1882) — that predate Clontech. In footnote 5 of its brief, McNeil suggests that Clontech is non-controlling as dictum. Yet McNeil fails to acknowledge that at least one district court, post-Clontech, has expressly held to the contrary. In DP Wagner Mfg. v. Pro Patch Sys., a case not cited by McNeil, the court explained as follows:

In Clontech, the Federal Circuit expressly stated that the term "unpatented article" "means that the article in question is not covered by at least one claim of each patent with which the article is marked," see Clontech, 406 F.3d at 1352 (emphasis added), and the Federal Circuit's construction is controlling in this case, notwithstanding the fact that other courts may have interpreted the term differently in the past.

434 F. Supp. 2d 445, 452 (S.D. Tex. 2006).

Moreover, in Pequignot v Solo Cup Co., 540 F. Supp. 2d 649, 654 (E.D. Va. 2008) ("Solo Cup I"), another post-Clontech case not cited by McNeil, the court performed an exhaustive analysis of applicable precedent, the ordinary meaning of the term "unpatented article," legislative structure and history, and public policy considerations before holding that "marking an article with an expired patent number is a false marking under 35 U.S.C. § 292(a)." Id. PUBPAT adopts in its entirety the Solo Cup I court's reasoning on these issues. To the extent this Court does not find Clontech controlling, PUBPAT respectfully submits that Solo Cup I is highly persuasive authority that supports the same result.

The Clontech / DP Wagner / Solo Cup I reasoning also complies with Supreme Court precedent, which has long recognized that patent expiration renders an article "unpatented." Bonito Boats, Inc. v. Thunder Craft, 489 U.S. 141 (1989) ("an item for which a patent has expired ... is unpatented"); see also Graver Tank & Mfg Co. v. Linde Air Products Co., 339 U.S.

605, 618 (1950) (Justice Douglas, dissenting opinion) (“manganese silicate had been covered by prior patents, now expired. Thus we end with a strange anomaly: a monopoly is obtained on an unpatented and unpatenable article.”).

Therefore, McNeil's motion to dismiss should be denied if any one of the accused products is marked with any expired patent number. In fact, *all* of the accused Tylenol products are falsely marked with *multiple* expired patent numbers; the 8 Hour Caplet and Arthritis Pain Caplet products were marked *only* with expired patents and the Arthritis Pain Geltabs were marked with both expired and unexpired patents. Thus, each of the products was "unpatented" under §292(a) and at least the markings of expired patent numbers qualify as false.

B. A Product Marked With A Patent On A Method Or Machine For Producing The Product Is “Unpatented” Under § 292(a) Because Such Method/Machine Patents Do Not “Cover” The Product Itself

Citing *not a single* §292 case, McNeil argues that “marking its products with patents that cover their method of manufacture and the apparatus used to make them ... cannot, as a matter of law, give rise to a claim of false patent marking.” McNeil Mem., 20-21. PUBPAT disagrees and suggests that, absent authority to the contrary, the Clontech rule applies. Under Clontech, marking a product with the numbers of patents that only cover methods or machines used to produce the product violates § 292, because no claim of those patents actually “covers” the product itself. To be sure, there may indeed be innovative ways to make a product, but a patent on those methods does not cover the product itself, because the product could also be produced by other ways that are not patented. And, a new machine for producing a product can itself be patented, but any such patent does not cover the product produced by the machine. Only patents on the product itself can cover the product and, thus, marking a product with numbers of patents

on methods or machines for producing it is false.

Regardless, the Court need not decide this question to deny McNeil's motion to dismiss. This entire issue only potentially applies to the Arthritis Pain Geltab products, because neither the 8 Hour Caplet nor the Arthritis Pain Caplet products are marked with any such method or machine patents. Those two products are only marked with expired patents and, as discussed above, their exclusively expired patent markings are false under § 292 and Clontech.

C. The “Canadian Patent” Is Irrelevant To The Issue Of Whether McNeil's False Markings Of Expired Patent Numbers Are Actionable Under §292(a)

McNeil's only excuse for marking its products with expired patents is its suggestion that they are covered by the claims of a “Canadian patent.” See McNeil Mem., 3-5. McNeil's sole basis for this assertion is that, “[t]he claims of the Canadian patent are identical to those of the '522 patent, so they protect the same subject matter claimed in the '522 patent.” McNeil Mem., 4. Even assuming McNeil's assertion were true, it would be a dubious reason to conclude that the “Canadian patent” covers the Arthritis Pain Caplet product because that product it is not marked with the '522 patent. Compl., ¶15. Further still, McNeil's own papers plainly reveal that the claims of the “Canadian patent” are *not identical* to those of the '522 patent. Compare Zalesin dec., Ex. 4 (Canadian patent) with Zalesin dec., Ex. 2 ('522 patent).⁸ Regardless, none of the products at issue in this case are marked with the “Canadian patent”.

Moreover, even if McNeil's factual assertions about the Canadian patent's claims were

⁸ The two patents don't even have the same number of claims. The Canadian patent has 17 claims (see Zalesin dec., Ex. 4, pages 24-31), whereas the '522 patent has only 7 claims, since claims 1-9 were issued in error and deleted by the Certificate of Correction attached to the patent itself (see Zalesin dec., Ex. 2, last page).

correct, the idea that a product could be considered “covered” under U.S. Patent Law merely because appropriately worded claims exist in a *foreign* patent is a stretch, and not good law. Relying exclusively on pre-Clontech cases, including principally Kor-CT, McNeil asserts that, “Every court that has addressed the issue has found that articles protected by foreign patents are not 'unpatented article[s]' within the meaning of the statute.” McNeil Mem., 19. This is simply not true. In DP Wagner, a case more recent than any cited by McNeil, the court specifically distinguished Kor-CT as applicable only to a general designation of a product as “patented,” not to a situation — like the present case — where the issue is “whether a product marked with multiple patent numbers, some of which are not applicable, is an 'unpatented' article.” DP Wagner, 434 F. Supp. 2d 445, 455 n.6.

All of the other cases cited by McNeil are similarly distinguishable. In Project Strategies Corp. v. Nat’l Comm. Corp., 948 F. Supp. 218, 225-27 (E.D.N.Y. 1996), the marking read, “PROTECTED WORLDWIDE BY U.S. AND FOREIGN PATENTS GRANTED AND PENDING,” which the court held did not violate § 292 because foreign patents were granted *and U.S. patents were pending*. Thus, what was said was true. Similarly, in Keystone Mfg. Co. v. Jaccard Corp., 394 F. Supp. 2d 543, 565 (W.D.N.Y. 2005), the marking was just “Pat.P.”, without any specific patent numbers.

To be sure, McNeil has cited no authority — and PUBPAT submits that there is none — for the proposition that one does not violate § 292 by marking a product with specific patent numbers of expired or inapplicable United States patents if it happens to be covered in a foreign country by an unexpired foreign patent. At best, the cases McNeil cites could be argued to support the proposition that it does not violate § 292 to label an article as “patented,” so long as

the article is patented outside the U.S. PUBPAT believes that even this narrower view of the cases cannot stand in light Clontech. More importantly, however, the Court need not reach this narrower issue of markings without patent number(s) to deny McNeil's motion. In the present case, all of the products identified in the complaint were marked with multiple, expired patent numbers.

D. The Statute Does Not Sanction Or Encourage McNeil's Behavior

McNeil's contention that falsely marking its products "helps" the public is just silly. McNeil Mem., 20. As detailed above, false marking causes significant public harm in a myriad of ways. Regardless, even if McNeil's assertion were true, it would not be a legitimate basis for reversing Congress' clear policy decision in implementing the false marking statute and rejecting the sound legal analysis set forth above on the issue of whether marking with an expired or inapplicable patent is false under § 292. On this issue, the Solo Cup I court said the following:

Solo argues that public policy is best served by construing § 292 to exclude liability for marking an article with an expired patent. According to Solo, such a marking provides three pieces of useful information:

(1) the patent's filing and issuing dates from which the date of patent expiration is apparent; (2) the patent specification, which provides information sufficient to enable a person of skill in the art to make and use the invention; and (3) the best mode for making and using the invention.

Def. Mem. in Support [10], at 9-10.

These interests are substantially outweighed by the potential harms such markings pose to the patent system. There is an "important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." Lear, Inc. v. Adkins, 395 U.S. 653, 670, 89 S. Ct. 1902, 23 L. Ed. 2d 610 (1969). In creating the patent system, Congress carefully weighed that interest against the need to incentivize the work of the inventor, allowing him to reap material rewards from his creativity. The Supreme Court has summarized this balancing act:

Congress has given to the inventor opportunity to secure the material rewards for his invention for a limited time, on the condition that he make full disclosure for the benefit of the public of the manner of making and using the invention, and that upon the expiration of the patent the public be left to use the invention.

Scott Paper Co. v. Marcalus Mfg. Co., 326 U.S. 249, 255, 66 S. Ct. 101, 90 L. Ed. 47, 1946 Dec. Comm'r Pat. 616 (1945) (emphasis added).

Patent markings are an essential component of this system. The "Patent No. XXX" imprint is, in effect, a "no trespassing" sign. Would-be inventors and consumers justifiably rely on such marks to assume that the patent holder retains control over how the article can be used, displayed, modified, or licensed. As the Supreme Court has observed, those markings "provide [the public] a ready means of discerning the status of the intellectual property embodied in an article of manufacture or design." Bonito Boats, 489 U.S. at 162 (emphasis added).

Giving the patent holder free reign to list expired patent numbers on articles would upset this delicate balance. The public could no longer assume "the status of the intellectual property" by the simple presence of a "Patent No. XXX" marking. Potential inventors and consumers would be forced to look up every patent marking to discern whether the patent was valid or expired, possibly leading some to shy away from using that article. These burdens, when considered in the aggregate, inhibit the free flow of ideas and "the benefits of the unrestricted exploitation" with respect to those articles that have entered the public domain. Scott Paper, 326 U.S. at 255; see also Clontech, 406 F.3d at 1356-57 (observing that a false marking "misleads the public into believing that a patentee controls the article in question . . . , externalizes the risk of error in the determination, placing it on the public rather than the manufacturer or seller of the article, and increases the cost to the public of ascertaining whether a patentee in fact controls the intellectual property embodied in an article").

Solo Cup I, 540 F. Supp. 2d at 653-54. PUBPAT could not agree more. Defining false marking to include marking with an expired or inapplicable patent is strongly in the public interest.

CONCLUSION

For all these reasons, McNeil's motion to dismiss should be denied. Plaintiff is requesting by letter concurrently herewith oral argument on this motion.

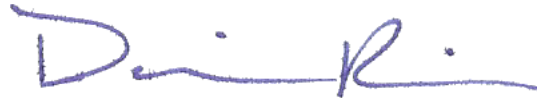
Respectfully submitted,

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November 5, 2009

CERTIFICATE OF SERVICE

This is to certify that all known counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system on November 5, 2009.

A handwritten signature in blue ink, appearing to read "D. Ravicher", is positioned above a horizontal line.

Daniel B. Ravicher (DR-1498)